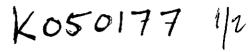
510 (k) Notification, ColActive™ Collagen Wound Dressing Covalon Technologies, Inc.



510 (k) Summary

1. Date Prepared: January 24, 2005

2. Submitter Covalon Technologies Inc.

405 Britannia Road East, Suite 106

Mississauga, L4Z 3E6 Ontario, CANADA Tel: (416) 944.3496 Fax: (416) 944.8520

Submission Correspondent:

Paul L. Guilbaud

Vice President and Director Wound & Tissue

Repair

14510 Kandi Court Largo, Florida 33774 Tel: (727) 595.8184 Fax: (727) 517.7005

Email: pguilbaud@covalon.com

4. Proprietary Name: ColActive™ Collagen Wound Dressing

Common Name: Wound Dressing

5. Regulatory Class: FRO

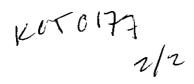
6. Statement of Substantial Equivalence:

ColActive™ Collagen Wound Dressings are substantially equivalent in materials of construction and intended use and identical in function to FIBRACOL PLUS Collagen Wound Dressing with Alginate manufactured by Johnson & Johnson Medical and SkinTemp Kollagen Wound Management Material manufactured by Biocore Medical Technologies.

7. Indications For Use:

ColActive™ Collagen Wound Dressing is indicated for the management of full and partial thickness wounds including:

510 (k) Notification, ColActive™ Collagen Wound Dressing Covalon Technologies, Inc.



- Pressure ulcers
- Diabetic ulcers
- Ulcers caused by mixed vascular etiologies
- Venous ulcers
- Second degree burns
- Donor and graft sites
- Abrasions
- Dehisced surgical wounds
- Traumatic wounds healing by secondary intention

8. Description:

ColActive™ Collagen Wound Dressing is an advanced wound care dressing composed of collagen and sodium alginate provided in a sterile sheet or rope form. ColActive™ Collagen Wound Dressings are pliable, absorbent dressings that absorb moisture such as wound fluid forming a gel, thus maintaining a moist environment at the wound surface that aids in the formation of granulation tissue and epithelialization. The dressings can be cut to fit specific wounds and are able to be layered for the management of deep wounds.

9. Biocompatibility:

ColActive™ Collagen Wound Dressings have been demonstrated to be safe wound dressings. To support the biocompatibility of these products, safety tests were conducted in accordance with ISO 10993 Part 1 Biological Evaluation of Medical Devices.

When all test results from tests conducted on ColActive™ Collagen Wound Dressings are taken into consideration as a whole, ColActive™ Collagen Wound Dressings have been demonstrated to be safe topical wound dressings in accordance with ISO 10993-1.



MAR 1 9 2007

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Mr. Paul L. Guilbaud Vice President Wound and Tissue Repair Covalon Technologies, Inc. 14510 Kandi Court Largo, Florida 33774

Re: K050177

Trade Name: ColActive™ Collagen Wound Dressing

Regulatory Class: Unclassified

Product Code: KGN Dated: March 29, 2005 Received: March 31, 2005

Dear Mr. Guilbaud:

This letter corrects our substantially equivalent letter of April 27, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act including requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Paul L. Guilbaud

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

All Mulkers

Mark N. Melkerson

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Page 1 of 1

PREMARKET NOTIFICATION INDICATIONS FOR USE STATEMENT

510 (k) Number:

k 0 50 17 7 Covalon Technologies, Inc.

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- Abrasions
- Dehisced surgical wounds
- Traumatic wounds healing by secondary intention

Prescription Use_	<u> </u>
(Per 21 CFR 801.	109)

Over-the-Counter OR

Use

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF

Concurrence of CDRH, Office of Device Evaluation (ODE)

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